patients who have failed existing approved therapies.

Information system (Sec. 407)

The conferees intend that the information system shall provide access to the information by the applicant under conditions set by the Secretary, except that access shall not be provided under any particular form of information system to any applicant until appropriate safeguards are in place to ensure that integrity and confidentiality of the information for which access is provided.

Education and training (Sec. 408)

The conference agreement authorizes the Centers of the FDA that conduct intramural research to provide fellowships and training to appropriate undergraduate, pre-doctoral, and/or post-doctoral candidates. In the past, FDA's Centers provided for a limited number of scientific training positions through Full Time Equivalent programs or interagency agreements with other federal agencies which have the statutory authority to hire trainees through third parties. However, many of the benefits of the training program have been reduced because FDA has not had specific direct authority to conduct and support them. In light of the additional overhead costs, reduced training flexibility, increased paperwork, and hiring delays that have resulted, it is increasingly difficult and impractical for FDA to hire trainees as FTE Service Fellows. As a result, the Intramural Research and Training Authority authorized here is intended to provide the FDA the authority to conduct and support directly the selection and training of fellows, allow more efficient use of appropriated funds by reducing overhead and other costs, and permit the training of such candidates as non-FTE positions. The conference agreement also provides similar authority for the Centers for Disease Control and Prevention.

Centers for education and research on therapeutics (Sec. 409)

The conference agreement establishes a demonstration program to conduct research and increase awareness of new products and ways to improve their effective use, and to increase awareness of risks of both new uses and combinations of therapies. In carrying out this demonstration program, the Secretary is directed to act through the Agency for Health Care Policy and Research (AHCPR) in consultation with the FDA Commissioner. The conferees designated AHCPR as the lead agency because of its expertise in the evaluation of the effectiveness of clinical care, its non-regulatory role, and its close working relationship with the health care community in the improvement of the quality of care. Accordingly, this section establishes a new Section 928 in Title IX of the Public Health Service Act, the authorizing statute for AHCPR.

To ensure appropriate coordination and to avoid unnecessary duplication, AHCPR is required to consult closely with the FDA in the development and operation of this demonstration program. The conferees expanded the focus of this demonstration to include ways to improve the effective use of drugs, biological products, and devices as well as risks of new combinations of such products and directed that the clinical information gained in the project would be provided to consumers as well as health care practitioners and insurers. Finally, the conferees direct AHCPR also to consider the appropriate use of products in meeting the purposes of this section.

Environmental impact review (Sec. 411)

The conferees believe that FDA's new procedures implementing the National Environmental Policy Act (NEPA) appropriately eliminate unnecessary paperwork and delays associated with prior agency practices. Section 411 makes clear that an environmental impact statement (EIS) prepared in accordance with those regulations will meet the requirements of NEPA. The conferees do not intend this section to preclude judicial review of EISs. The conferees understand that the FDA may modify its regulations periodically, in consultation with the Council on Environmental Quality and the FDA's authorizing committees, as new circumstances or information warrants.

Because the Clean Air Act authorizes production of limited quantities of Class I and Class II substances for use in medical devices, there will be a continuing, but limited, supply of these substances. The EPA shall not dictate, promote or otherwise encourage a policy preference for disposal by incineration of the contents of metered-dose inhalers, but instead allow such contents to be recaptured, recycled or reused consistent with section 608(a)(3) of the Clean Air Act until such time that Congress conducts oversight hearings into the issue.

National uniformity for nonprescription drugs and cosmetics (Sec. 412)

Confidentiality of OTC company self-audits

Public policy should encourage drug manufacturers to conduct audits of their activities to candidly alert management to potential problems so that they can be addressed quickly and effectively. If FDA were to assert routine access to these audits, it would create serious disincentives to conducting appropriate audits and preparing thorough reports of the results. FDA already has a policy of not ordinarily requesting audit reports, which is set forth in compliance policy guide (#7151.02, Sec. 130.300) that applies to prescription drug firms. It is expected that OTC drug firms would be subject to the same compliance policy guide. Thus, during routine inspections of OTC drug establishments, FDA would not be expected to request or to review or copy reports and records that result from the firm's own audits and inspections of its operations to assure compliance with applicable FDA requirements such as good manufacturing practice (GMP) regulations. FDA would reserve the right to review such audits in certain limited circumstances as outlined in the compliance guide.

OTC and cosmetics inspection

The conferees intend that FDA exercise its new records inspection authority fairly and carefully, especially with regard to inspections at facilities that manufacture products that are both cosmetics and over-the-counter drugs. Cosmetic products that are also OTC drugs will, under the provisions of this bill, benefit from full national uniformity relating to all regulatory requirements, including those associated with ingredients, labeling, and packaging. Therefore, under these provisions, manufacturers of such OTC products will be subject to records inspection by FDA. The conferees want to make clear that any records inspection applies only to those products for which there is full national uniformity. This new records inspection authority applies only to products determined to be over-the-counter drugs. It does not apply to products that are solely cosmetics.

In the case of an inspection at a facility which deals both with cosmetic products that are OTC drugs and those that are not, FDA inspectors do not have access to any records relating to the cosmetic products. Further, the conferees want to make clear that there is no records inspection authority under these provisions for facilities dealing exclusively with cosmetics.

Finally, the conferees expect that FDA will provide sufficient time and guidance to the over-the-counter drug industry prior to initiating any program of records inspection and in the early stages of implementing this new requirement.

Effect of national uniformity on state enforcement ''little FTC'' laws

All states have laws prohibiting false and misleading advertising, modeled on the Federal Trade Commission Act. These laws have been applied to prohibit unsubstantiated claims for nonprescription drugs and cosmetics, and to require corrective advertising. This provision is not intended to preempt the application of these laws under such circumstances.

The Conference Committee intends to make clear that ''Little FTC'' laws, as they have historically been written and applied, are not preempted. The scope of national uniformity is modified to only apply to state requirements that relate to labeling and packaging or, if they go beyond labeling and packaging, to requirements relating to warnings. Thus, advertising issues relating to claims substantiation, fair balance, and misleading or deceptive claims are outside the scope of preemption.

Effect of national uniformity on state food labeling laws

This provision is not intended to pre-empt or prohibit States from regulating the labeling of food which derives from animals treated with non-prescription drugs. Nor are these provisions intended to void State regulations on the use of these drugs.

Product classification (Sec. 416)

Subsections (b) and (c) have been amended to make clear that FDA may only modify product classifications for public health reasons based on scientific information.

TOM BLILEY,
MICHAEL BILIRAKIS,
JOE BARTON,
JAMES GREENWOOD,
RICHARD BURR,
ED WHITFIELD,
JOHN D. DINGELL,
SHERROD BROWN,
HENRY A. WAXMAN,
RON KLINK,
Managers on the Part of the House.

JIM JEFFORDS,
DAN COATS,
JUDD GREGG,
BILL FRIST,
MIKE DEWINE,
EDWARD M. KENNEDY,
CHRISTOPHER DODD,
TOM HARKIN,
BARBARA A. MIKULSKI,
Managers on the Part of the Senate.

LEAVE OF ABSENCE

By unanimous consent, leave of absence was granted to:

Mr. UNDERWOOD (at the request of Mr. GEPHARDT) for today and the balance of the week, on account of official business.

Mr. YATES (at the request of Mr. GEPHARDT) for November 8 after 12 noon and November 9, on account of personal reasons.

SENATE BILLS AND CONCURRENT RESOLUTION REFERRED

Bills and a concurrent resolution of the Senate of the following titles were taken from the Speaker's table and, under the rule, referred as follows:

S. 508. An act to provide for the relief of Mai Hoa ''Jasmin'' Salehi; to the Committee on the Judiciary.

S. 759. An act to amend the State Department Basic Authorities Act of 1956 to require the Secretary of State to submit an annual report to Congress concerning diplomatic immunity; to the Committee on International Relations.

S. 857. An act for the relief of Roma Salobrit; to the Committee on the Judiciary.

S. 1189. An act to increase the criminal penalties for assaulting or threatening Federal judges, their family members, and other public servants, and for other purposes; to the Committee on the Judiciary.

S. 1304. An act for the relief of Belinda McGregor; to the Committee on the Judiciary.

S. 1487. An act to establish a National Voluntary Mutual Reunion Registry; to the Committee on Ways and Means.

S. 1507. An act to amend the National Defense Authorization Act for Fiscal Year 1998 to make certain technical corrections; to the Committee on National Security.

S. Con. Res. 58. Concurrent resolution expressing the concern of Congress over Russia's newly passed religion law; to the Committee on International Relations.

BILL AND JOINT RESOLUTION PRESENTED TO THE PRESIDENT

Mr. THOMAS, from the Committee on House Oversight reported that that committee did on the following dates present to the President, for his approval, a bill and a joint resolution of the House of the following titles:

On November 8, 1997:

H.R. 2264. An act making appropriations for the Departments of Labor, Health and Human Services, and Education, and related agencies for the fiscal year ending September 30, 1998, and for other purposes.

On November 9, 1997:

H.J. Res. 104. Joint resolution making further continuing appropriations for the fiscal year 1998, and for other purposes.

ENROLLED BILLS AND JOINT RESOLUTION SIGNED

Mr. THOMAS, from the Committee on House Oversight, reported that that committee had examined and found truly enrolled bills and a joint resolution of the House of the following titles, which were thereupon signed by the Speaker:

H.R. 1747. An act to amend the John F. Kennedy Center Act to authorize the design and construction of additions to the parking garage and certain site improvements, and for other purposes.

H.R. 1787. An act to assist in the conservation of Asian elephants by supporting and providing financial resources for the conservation programs of nations within the range of Asian elephants and projects with demonstrated expertise in the conservation of Asian elephants.

H.R. 2731. An act for the relief of Roy Desmond Moser.

H.R. 2732. An act for the relief of John Andre Chalot.

H.J. Res. 104. Joint resolution making further continuing appropriations for the fiscal year 1998, and for other purposes.

SENATE ENROLLED BILLS SIGNED

The SPEAKER announced his signature to enrolled bills of the Senate of the following titles:

S. 813. An act to amend chapter 91 of title 18, United States Code, to provide criminal penalties for theft and willful vandalism at national cemeteries.

S. 1377. An act to amend the act incorporating the American Legion to make a technical correction.

ADJOURNMENT

Mr. SOLOMON. Mr. Speaker, I move that the House do now adjourn.

The motion was agreed to; accordingly (at 2 o'clock and 2 minutes a.m.), under its previous order, the House adjourned until Wednesday, November 12, 1997, at 12 noon.

EXECUTIVE COMMUNICATIONS, ETC.

Under clause 2 of rule XXIV, executive communications were taken from the Speaker's table and referred as follows:

5818. A letter from the Director, Office of Regulatory Management and Information, Environmental Protection Agency, transmitting the Agency's final rule—Corn Gluten; Exemption from the Requirement of a Tolerance [OPP–300505A; FRL–5750–3] (RIN: 2070–AB78) received November 6, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Agriculture.

5819. A letter from the Assistant Secretary (Installations and Environment), Department of the Navy, transmitting notification of intent to study a commercial or industrial type function performed by 45 or more civilian employees for possible outsourcing, pursuant to 10 U.S.C. 2304 nt.; to the Committee on National Security.

5820. A letter from the Assistant Secretary (Reserve Affairs), Department of Defense, transmitting a report on the progress of the study on the means of ensuring uniformity in provision of medical and dental care for members of reserve components, pursuant to Public Law 104—201, section 746(b) (110 Stat. 2602); to the Committee on National Security.

5821. A letter from the Assistant to the Board, Board of Governors of the Federal Reserve System, transmitting the Board's final rule—Reserve Requirements of Depository Institutions [Regulation D; Docket No. R–0980] received October 31, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Banking and Financial Services.

5822. A letter from the Director, Office of Rulemaking Coordination, Department of Energy, transmitting the Department's ''Major'' final rule— Energy Conservation Program for Consumer Products: Final Rule Regarding Energy Conservation Standards for Room Air Conditioners [Docket Nos. EE-RM–90–201 and EE-RM–93–801–RAC] (RIN: 1904–AA38) received November 8, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Commerce.

5823. A letter from the Director, Office of Regulatory Management and Information, Environmental Protection Agency, transmitting the Agency's final rule—Approval and Promulgation of State Plans for Designated Facilities and Pollutants: Florida [FL–70–1–9738a; FRL–5920–3] received November 7, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Commerce.

5824. A letter from the Director, Office of Regulatory Management and Information, Environmental Protection Agency, transmitting the Agency's final rule—Approval and Promulgation of Implementation Plans; California State Implementation Plan Revision, South Coast Air Quality Management District [CA 034–0048; FRL–5917–5] received November 7, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Commerce.

5825. A letter from the Director, Office of Regulatory Management and Information, Environmental Protection Agency, transmitting the Agency's final rule—Approval and Promulgation of Implementation Plans; California State Implementation Plan Revision, San Diego County Air Pollution Control District, Ventura County Air Pollution Control District [CA 083–0053a; FRL–5911–4] received November 6, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Commerce.

5826. A letter from the Director, Office of Regulatory Management and Information, Environmental Protection Agency, transmitting the Agency's final rule—Michigan: Final Authorization of Revisions to State Hazardous Waste Management Program [FRL–5918–8] received November 6, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Commerce.

5827. A letter from the Director, Office of Regulatory Management and Information, Environmental Protection Agency, transmitting the Agency's final rule—Ambient Air Quality Surveillance for Lead [AD-FRL–5903–5] (RIN: 2060–AF71) received November 6, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Commerce.

5828. A letter from the Director, Office of Regulatory Management and Information, Environmental Protection Agency, transmitting the Agency's final rule—Removal of Requirement in Gasoline Deposit Control Additives Rule Regarding the Identification of the Oxygenate Content of Transferred Gasoline [FRL–5917–9] received November 6, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Commerce.

5829. A letter from the AMD—Performance Evaluation and RECORDS Management, Federal Communications Commission, transmitting the Commission's final rule—Amendment of the Commission's Rules to Establish a Radio Astronomy Coordination Zone in Puerto Rico [ET Docket No. 96–2, RM–8165] received November 8, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Commerce.

5830. A letter from the AMD—Performance Evaluation and RECORDS Management, Federal Communications Commission, transmitting the Commission's final rule—Amendment of Part 15 of the Commission's Rules to permit operation of biomedical telemetry devices on VHF TV channels 7–13 and on UHF TV channels 14–46 [ET Docket No. 95–177] received November 8, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Commerce.

5831. A letter from the Director, Regulations Policy and Management Staff, Office of Policy, Food and Drug Administration, transmitting the Administration's final rule—Secondary Direct Food Additives Permitted in Food for Human Consumption; Milk-Clotting Enzymes [Docket No. 93F–0461] received November 6, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Commerce.

5832. A letter from the Chairman, Nuclear Regulatory Commission, transmitting a report on the nondisclosure of safeguards information for the quarter ending September 30, 1997, pursuant to 42 U.S.C. 2167(e); to the Committee on Commerce.

5833. A letter from the Director, Defense Security Assistance Agency, transmitting notification concerning the Department of the Army's Proposed Letter(s) of Offer and Acceptance (LOA) to Egypt for defense articles and services (Transmittal No. 98–21), pursuant to 22 U.S.C. 2776(b); to the Committee on International Relations.

5834. A letter from the Director, Defense Security Assistance Agency, transmitting